

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

MORTON GROVE)
PHARMACEUTICALS, INC.)
)
Plaintiff,)
)
v.)
)
THE NATIONAL PEDICULOSIS)
ASSOCIATION, INC.)
)
Defendants.)
)
)

No: 08-CV-1384

Judge Bucklo
Magistrate Judge Mason

**MORTON GROVE PHARMACEUTICALS, INC.’S
REPLY IN SUPPORT OF ITS MOTION TO DISMISS
THE NATIONAL PEDICULOSIS ASSOCIATION, INC.’S COUNTERCLAIM**

The NPA’s attempt to transform pure political speech—including letters written by third-party medical and scientific experts to members of the Michigan legislature—into “commercial advertising” must be rejected. The NPA’s claim that these statements are advertisements flies in the face of well-established Seventh Circuit precedent (which the NPA refuses to acknowledge), common sense, the judgment of the FDA, and the face of the documents at issue, which all plainly focus on a legislative policy debate. Given the important First Amendment political overtures present here, this is the wrong case to stretch the Lanham Act to new and creative heights.

The NPA’s counterclaim also must be dismissed because neither it nor the NPA’s response brief demonstrate that the NPA’s claims are conceivable, much less “plausible” as is required by *Bell Atl. Corp. v. Twombly*. 127 S. Ct. 1955, 1974 (2007). The NPA fails to acknowledge this standard, let alone meet it. All the NPA offers to support its allegations of harm is speculation—that Morton Grove’s statements “*could* result in increased sales at the

expense of NPA’s sales”—and this is insufficient. *See Midwest Canvas Corp. v. Commonwealth Canvas, Inc.*, 2008 WL 162757, at *2 (N.D. Ill. Jan. 16, 2008) (applying *Twombly* in dismissing a false advertising claim under the Lanham Act).

I. THE NPA’S CLAIMS CANNOT SURVIVE BECAUSE THE NPA HAS NOT SUFFICIENTLY PLED THAT THE STATEMENTS AT ISSUE ARE “COMMERCIAL ADVERTISEMENTS”

In arguing that it has pled commercial advertising—solely by referencing Morton Grove’s lobbying campaign, but not any of Morton Grove’s actual product advertisements produced in discovery—the NPA ignores applicable precedent. In this Circuit, false statements must occur in “commercial advertising or promotion.”¹ *First Health Group Corp. v. BCE Emergis Corp.*, 269 F.3d 800, 803 (7th Cir. 2001).

The Seventh Circuit has defined advertising as “a form of promotion to anonymous recipients, as distinguished from face-to-face communication. In normal usage, an advertisement read by millions (or even thousands in a trade magazine) is advertising, while a person-to-person pitch by an account executive is not.” *Id.* at 803-04. Further, it is “a subset of persuasion and refers to dissemination of prefabricated promotional material.” *Id.* at 804 (citation omitted).

Here, there is no basis for NPA’s claim that the “Lindane Information Fact Checker” portion of www.lindane.com, five lobbying letters written to key opinion leaders involved in the Michigan political debate regarding pending legislation, and two letters written to a Michigan assemblywoman constitute a promotional campaign. These materials do not promote

¹ As the NPA itself has argued in previous pleadings, “This phrase limits the scope of Lanham Act claims to those false statements of fact that are: ‘(1) commercial speech, (2) made for the purpose of influencing consumers to buy defendant’s goods or services, and (3) . . . disseminated sufficiently to the relevant purchasing public.’ *Gmurzynski v. Hutton*, 355 F.3d 206, 210-11 (2d Cir. 2004) (per curiam).” (Case 1:06-cv-3815 Docket Entry 59, Def.’s Br. in Supp. of its Mot. to Dismiss Pl.’s Am. Compl. at 12.) Under that standard, none of the statements the NPA attributes to Morton Grove are actionable.

the sale of the product, do not reference or link to information that would directly or indirectly lead to a commercial transaction, but instead contain a host of policy-related information. The NPA invites this Court to ignore common sense and the face of the exhibits themselves, and to instead take a strained reading of the attorney argument contained in the NPA's pleading. This invitation should be rejected.

A. The Letters to Michigan Medical Organizations Regarding Michigan House Bill 4569 Are Not Commercial Advertisements

According to the standards articulated in *First Health Group Corp.*, Morton Grove's lobbying letters to five Michigan key opinion leaders regarding proposed legislation are not commercial advertising. The NPA predicates its claims on these letters which were never posted on Morton Grove's lobbying website (www.lindane.com) or its promotional website (www.mgp-online.com)² and were never broadly circulated.

These letters are *not* "promotion to anonymous recipients" and are not even akin to the "person-to-person pitch by an account executive" that the Seventh Circuit has held was insufficient to constitute commercial advertising. *See First Health Group Corp.*, 269 F.3d at 803-04. These letters were targeted to five key opinion leaders central to the ongoing legislative debate—a far cry from the "dissemination of prefabricated promotional material." *See id.* at 804. In order to be advertising, the dissemination must have an "element of publicity" involved—an element these letters plainly lack. *Midwest Canvas Corp.*, 2008 WL 162757, at *3.³

² This website now directs to Morton Grove's new parent company's website, <http://www.wockhardtusa.com/>.

³ The case law the NPA cites predates *First Health* and does not control. The NPA cites *Republic Tobacco v. North Atlantic Trading Co.*, 1999 WL 261712 (N.D. Ill. Apr. 9, 1999) and *Health Care Compare Corp. v. United Payors & United Providers, Inc.*, 1998 WL 122900 (N.D. Ill. Mar. 13, 1998); however, both these cases were decided before the Seventh Circuit defined advertising in *First Health Group Corp.* as "a form of promotion to anonymous recipients, as distinguished from face-to-face communication." 269 F.3d at 803. In the face of this clear and unambiguous precedent, the NPA can

Nor does the counterclaim plead that these letters were sent to Morton Grove customers—nor could it. According to Seventh Circuit law, “letters sent to customers do not come within the scope of § 43(a)(1)(B)—which is limited to false or misleading ‘commercial advertising or promotion’ and does not cover all deceitful business practices.” *ISI Intern., Inc. v. Borden Ladner Gervais LLP*, 316 F.3d 731, 733 (7th Cir. 2003) (citing *First Health Group Corp.*, 269 F.3d 800).

B. Letters Written by Third-Party Medical Experts to the Michigan Legislature Are Not Commercial Advertisements

The letters written by Doctors Hebert and Shwayder to the Michigan legislature concerning proposed legislation are also not commercial advertisements under the *First Health Group Corp.* standard. These letters on their face—even the “re” line says “House Bill 4569”—have an obvious legislative purpose. The letters contain the doctors’ opinions and their experiences with Lindane medications. They are nationally recognized pediatric dermatologists who felt strongly about exercising their First Amendment rights to say that a Lindane ban posed no significant public health risks.⁴ Furthermore, though Morton Grove obviously does not disagree with these statements, they are not even statements “by the defendant” as required by the Lanham Act—their posting on www.lindane.com with full attribution under the heading “**Medical & Scientific Opinions**,” on a page entitled “Points of View on Lindane,” hardly renders them anything other than medical and scientific opinions. *See Part IV, infra.*

only look to other circuits to bolster its hollow arguments. *See Semco, Inc. v. Amcast, Inc.*, 52 F.3d 108 (6th Cir. 1995); *Healthport Corp. v. Tanita Corp. of America*, 2008 WL 2224398 (D. Or. May 23, 2008).

⁴ The cases the NPA cites to suggest that these letters could somehow be sales pitches are unpersuasive and not on point. In *Criticare Systems, Inc. v. Nellcor, Inc.*, a letter was shown to members of hospital task force interested in purchasing the product at issue—an obvious commercial use. 856 F. Supp. 495, 498 (E.D. Wis. 1994). And, in *Patient Transfer Systems, Inc. v. Patient Handling Solutions, Inc.*, the letters were sent to prospective customers—again, commercial use (and as discussed above, not actionable in this Circuit). 2001 WL 936641, 18, 20 (E.D. Pa. Aug. 16, 2001). Neither of these cases involved letters directed to legislative bodies.

C. Statements on Morton Grove's Lobbying Website Are Not Commercial Advertisements

The NPA has not and cannot plead facts to overcome what is apparent from the face of www.lindane.com.⁵ The website⁶ was independently vetted by an editorial panel of thought leaders to ensure accuracy and truthfulness. It is focused on political issues relevant to lindane and is targeted to legislators and healthcare policy makers. It contains no links to any Morton Grove website, or the Alliant website, www.lindane4lice.com, and does not counsel or suggest to the viewer that he or she should consult their physician about using lindane. It is not a website designed for those looking for lice or scabies treatment options, but is instead a website for those seeking only specific information about the safety and risk profile of lindane medications from a legislative policy perspective.

The NPA's attempt to transform Morton Grove's lobbying website into a commercial advertisement must fail.⁷ Each of these three statements appears on the webpage entitled "Lindane Information Fact Checker." On its face, this page is *informational* and not an *advertisement*. In fact, the very first sentence on this page begins: "**Groups seeking to ban** the medical use of lindane" This highlights the blatant legislative purpose behind Morton Grove's statements. And, while the NPA attempts in its response brief to distinguish

⁵ Courts may look to exhibits attached to the claim in deciding a motion to dismiss, and the exhibits control over any contradictory allegations in the body of the claim. *In the Matter of Wade*, 969 F.2d 241, 249-50 (7th Cir. 1992).

⁶ The websites www.lindane.com and www.lindanetruth.com are one and the same. The www.lindane.com website may be accessed by that web address or the web address www.lindanetruth.com. There are simply two different domain names for the same site. (See Affidavit of Ralph J. Hodosh, Docket Entry 44-2, Exhibit P at ¶ 4.) Because these two addresses lead to the same web pages, Morton Grove refers simply to www.lindane.com throughout this brief.

⁷ The NPA's allegation that www.lindane.com is a commercial advertisement largely hinges on puffery authored by Closerlook, which was not accurate or approved by Morton Grove. Closerlook's statement was inaccurate, apparently developed by a low-level staffer not involved in the project, and has long since been removed from Closerlook's website at Morton Grove's request. In fact, Closerlook was not hired as a "marketing partner" but for its technical expertise in constructing websites; it had zero input relative to content, and the referenced puffery is outside the pleadings and not even referenced in the counterclaim.

factually *Midwest Canvas*, the NPA does not dispute that it sets forth the appropriate legal test—“an analysis of whether the language is motivated primarily by commercial concerns, or whether there are sufficient non-commercial motivations.” 2008 WL 16757, at *5. Likewise, nowhere in the NPA’s response brief does the NPA dispute that Morton Grove had “sufficient non-commercial motivations” for www.lindane.com, namely to support the company’s lobbying efforts. In fact, the NPA *recognizes* this “non-commercial motivation” in its own counterclaim—“Since 2002, bills to ban pharmaceutical uses of the chemical lindane have been introduced in several states, including at least New York, Michigan, and Illinois.” (Counterclaim ¶ 17.)

In addition, www.lindane.com, unlike all of the television, print, and internet advertisements for pharmaceutical products, nowhere states or suggests “Talk with your doctor about lindane. . . ” This contrasts sharply with, for example, Pfizer’s Viagra, one of the most advertised drugs on the market, whose website contains an entire section entitled “Getting a Prescription.” See <http://www.viagra.com/content/getting-viagra-prescription.jsp> (“There are a lot of great reasons to talk to your doctor about VIAGRA. So what are you waiting for? In this section, we’ve outlined everything you need to know about getting a prescription.”). Rather than promote use of Lindane medications on www.lindane.com, Morton Grove openly tackles the most outlandish allegations about the product, such as “Does a single treatment of lindane pollute 6 million gallons of water?” and “Do lindane medications cause cancer”—issues no pharmaceutical company would highlight in a “commercial advertisement.” It is for these reasons, the FDA itself has not found www.lindane.com to be a commercial advertisement. (Ex. A, Ltr. from D. Beers to FDA, which the FDA has apparently accepted.)

II. THE NPA'S CLAIMS IMPLICATE FIRST AMENDMENT POLITICAL SPEECH, WHICH ARGUES STRONGLY AGAINST APPLICATION OF THEY LANHAM ACT

The NPA's characterization of the statements it attributes to Morton Grove ignores the context, content, and audiences for those statements. It belies logic to argue that letters from respected thought leaders to a legislative committee about the status of a bill could be anything but political speech. The documents speak for themselves and they control over contradictory allegations in the claim. *In the Matter of Wade*, 969 F.2d at 249-50. For example, the letters make apparent that www.lindane.com was intended to be a source of additional information for those involved in the legislative debate—"Our goal is to set the record straight so that informed decisions can be just that. . . . Additional information can be found at www.lindane.com." (Counterclaim Ex. B.) While the NPA may offer attorney argument to the contrary, such conjecture cannot overcome the facts as stated on the face of the documents at issue.⁸

It cannot be disputed that there at lease some (if not exclusively) "sufficient non-commercial motivations" for www.lindane.com. *Midwest Canvas Corp.*, 2008 WL 162757, at *5. Indeed, the *Midwest Canvas* test has its roots in Supreme Court precedent. Applying that precedent in a Lanham Act case, the court in *Monotype Corp. v. Simon & Schuster Inc.*, noted:

[W]here the main purpose of a work is non-commercial and the commercial and non-commercial components of "a single speech are inextricably intertwined, we cannot parcel out the speech, applying one test to one phrase and another test to another phrase. . . . Therefore, we apply our test for fully-protected expression."

⁸ The NPA's citation to *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60 (1983) is no more persuasive than its attorney argument. *Bolger* was not a Lanham Act case, but instead was a case where a manufacturer successfully challenged the constitutionality of a unsolicited mail statute on First Amendment grounds. There, all parties agreed that the mailings were advertisements and were commercially motivated. Thus, this case is not controlling or instructive.

2000 WL 1852907, at *7 (N.D. Ill. Sept. 8, 2000) (quoting *Riley v. Nat'l Fed'n of the Blind*, 487 U.S. 781, 795-96 (1988)) (App. Tab 1). The *Monotype Corp.* court concluded that even if two allegedly false statements qualified as commercial speech, because they were in a much larger guide that was non-commercial overall, the entire guide fell outside the scope of the Lanham Act. *Id.* Likewise here, even if the Court concluded that www.lindane.com was motivated by some commercial concerns (it was not), it is still primarily political speech, and is thus not actionable under the Lanham Act or the UDTPA. For this additional reason, the NPA's counterclaim must be dismissed.

III. THE NPA'S CLAIMS CANNOT SURVIVE BECAUSE IT FAILED TO PROPERLY PLEAD CAUSATION

Making these claims even more problematic is the NPA's failure to plead causation. The NPA offers nothing to "nudge[its] claims across the line from conceivable to plausible." *Twombly*, 127 S. Ct. at 1974. Instead it offers only insufficient speculation. *Midwest Canvas Corp.*, 2008 WL 162757, at *2. This alone is a sufficient basis to dismiss the NPA's entire counterclaim. *See Twombly*, 127 S. Ct. at 1973 n.14 (stating "the complaint warranted dismissal because it failed *in toto* to render plaintiffs' entitlement to relief plausible").

Specifically, the NPA has not pled, as it must for its Lanham Act claim, that it "has been or is likely to be injured *as a result of* the false statement," by either diversion of sales or loss of goodwill. *See Hot Wax, Inc. v. Turtle Wax, Inc.*, 191 F.3d 813, 819 (7th Cir. 1999) (emphasis added). Nowhere in the NPA's counterclaim does the NPA explain how Morton Grove's statements have harmed the NPA. For example, the NPA cannot and has not pled that statements to legislators by Drs. Shwayder or Paller caused it any harm. Much the same, the NPA fails to state how the five letters by Dr. Lee to organizations involved in the Michigan legislative debate caused it Lanham Act injury. Rather than meet its burden, the NPA shies away

from it, offering only a qualified tender of causation: the statements the NPA attributes to Morton Grove “**could result** in increased sales at the expense of NPA’s sales,” and “NPA’s services and goodwill . . . **may be** injured.” (Def.’s Br. 18 (emphases added).)

The NPA’s failure to plead any actual injury is particularly problematic given that most of the statements at issue are medical and scientific opinions—in the case of Doctors Shwayder and Hebert, medical and scientific opinions which are on their face formed by their own experience. *See Groden v. Random House, Inc.*, 61 F. 3d 1045, 1051 (2nd Cir. 1995) (stating “statements of opinion are generally not the basis for Lanham Act liability”).

And, as these statements are not alleged to be literally false (for example, the NPA never claims that Dr. Shwayder lied when he said he used Lindane on his family), the NPA must show consumer deception or at least some direct evidence of injury. *See Tropicana Prods., Inc. v. Vero Beach Groves, Inc.*, No. 92-11044 (D. Mass Oct. 16, 1992)⁹ (failure to have a survey or other plausible economic evidence of injury justified granting motion to dismiss Lanham Act counterclaim); *Novartis Consumer Health v. Johnson & Johnson*, 129 F. Supp.2d 3551 (D.N.J. 2000). Nowhere in the NPA’s Counterclaim do they plead any facts relating to any analysis, survey, or other evidence supporting the bare allegations of speculative harm, much less actual or likely consumer deception.¹⁰ This Court should dismiss the NPA’s counterclaim given the lack of any well-pled or economically plausible injury.

⁹ Despite diligent efforts, counsel has been unable to locate a copy of this opinion. Counsel will provide a copy should one become available. Attached are the memorandum that was filed in support of the motion to dismiss the counterclaim at issue, with the relevant arguments on pages 7-9, and the docket listing showing the motion was granted, at entry 89 (App. Tabs 2-3) (exhibits to memorandum omitted).

¹⁰ Making any bare claim of “injury” even more economically implausible is the Lindane Shampoo product label: “Lindane Shampoo should be used in the context of an overall lice management program that includes . . . Manual removal of nits using a comb designed for this purpose and/or individual removal...”. *See* <http://www.fda.gov/cder/foi/label/2003/006309shampoolbl.pdf>. While the NPA has forced itself upon Morton Grove as a competitor by aggressively positioning their branded comb products as a **replacement** to Lindane Shampoo and affirmatively seeking to take sales away from Morton Grove

IV. THE NPA'S CLAIMS CANNOT SURVIVE TO THE EXTENT THEY ARE PREDICATED ON MEDICAL AND SCIENTIFIC OPINIONS

Incredibly, the NPA suggests that “[i]t is difficult to see what constitutionally protected opinion is involved” with the statements made by Drs. Shwayder and Hebert. To do so, it must ignore the words used in the statements and the sentiment behind them—seeking on their face to avoid a Michigan ban on Lindane. Dr. Shwayder indicates that he is discussing his personal experiences: “[m]y training in both pediatrics and dermatology allows me to judge this issue.” (Countercl. ¶ 68.) Dr. Hebert does the same: “I have personally used this medication many times . . . and believe that it is both safe and effective when used according to the package insert.” (Countercl. ¶ 74.) These are the doctors’ own opinions,¹¹ formed by their own experiences, and cannot be labeled as true or false. They are thus not actionable, and to the degree the NPA’s claims are premised upon them, the claims must be dismissed. *See Groden*, 61 F.3d at 1051 (stating “statements of opinion are generally not the basis for Lanham Act liability”).

V. THE NPA’S UDTPA CLAIM CANNOT SURVIVE

The NPA’s UDTPA claim cannot survive a motion to dismiss. It fails because the UDTPA claim fails, and it fails with regard to multiple statements by the NPA’s own admission. First, because the NPA’s Lanham Act claim fails, the UDTPA claim must fail as well. The NPA agrees that the legal analysis for a UDTPA claim should use the same principles as the analysis for a Lanham Act claim.

(despite the fact that they have no data to support such a recommendation). Conversely, the increased use of Lindane Shampoo would not be expected to cause economic harm to NPA by decreasing use of its comb products as combing more generally is recommended as an *adjunct* to lindane therapy.

¹¹ The NPA’s repeated references to the FDA’s position on lindane medications are mere smoke and mirrors. The NPA does not have standing to bring claims predicated on Morton Grove’s product labeling, because such matters are regulated by the FDA, not private parties. *See* 21 U.S.C. § 337; *Pac. Trading Co. v. Wilson & Co.*, 547 F.2d 367, 368 (7th Cir. 1976).

Second, the NPA's response brief again retreats from the NPA's counterclaim, admitting that has no UDTPA claim for seven of the eleven statements at issue. (Def.'s Br. 19 ("NPA is suing only on the portion of those statements that relate to Morton Grove's products.")) This differs from the counterclaim, which purports to seek relief on all 11 statements. (Docket Entry 37, at paragraph 133 ("The statement set forth in paragraphs 48-49, 51, 63, 68-70, 73-74, 111, and 113 violate several sections of the Illinois Deceptive Trade Practices Act, 815 ILCS 510/2, including section (a)(5) and (a)(12).")) As such, at a minimum, the statements that do not relate to Morton Grove's products: paragraphs 68-70 and 73-74 (doctors' personal experiences) and paragraphs 111 and 113 (statements on www.lindane.com about the NPA), by the NPA's own admission, must now be dismissed.

Further, the NPA brought its counterclaim under UDTPA sections (5) and (12), but now, in a further attempt to play fast and loose in this briefing, seeks to re-plead under section (8) via a response brief. As noted in the preceding paragraph, the NPA alleged the statements violated "several sections" of the UDTPA, "including section (a)(5) and (a)(12)." (Counterclaim at 53.) Thus, the NPA must prove that Morton Grove "represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he or she does not have," 815 ILCS 510/2(a)(5), or "engages in any other conduct which similarly creates a likelihood of confusion or misunderstanding," 815 ILCS 510/2(a)(12). Disparagement of another's goods, services, or business is addressed by section (8) (persons engage in deceptive trade practices where the person "disparages the goods, services, or business of another by false or misleading representation of fact"). The NPA *never* pled that Morton

Grove's statements violated section (8). As such, any attempt to bring such a claim must also fail.

CONCLUSION

In order to defeat Morton Grove's motion to dismiss its counterclaim, the NPA *must* show that the statements at issue (the "Lindane Information Fact Checker" portion of www.lindane.com, five lobbying letters written to key opinion leaders involved in the Michigan political debate regarding pending legislation, and two letters written to a Michigan assemblywoman) (1) were *not* motivated by any legitimate non-commercial concerns (i.e., lobbying), (2) constitute "a form of promotion to anonymous recipients . . . of prefabricated promotion material," (3) were not an exercise of Morton Grove's and Doctors Hebert's and Shwayder's First Amendment rights, and (4) plausibly (not conceivably) caused the NPA actual injury. The NPA cannot clear a single one of these hurdles. In fact, any argument that it could is not even colorable or made in good faith. It was for this reason that Morton Grove suggested the Court considers its authority to sanction the NPA *sua sponte* under the guise of Rule 11. Morton Grove itself chose not to pursue an affirmative motion seeking sanctions, but reserves all rights.

Dated: August 7, 2008

Respectfully Submitted,

MORTON GROVE PHARMACEUTICALS, INC.

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CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of August 2008, I caused a copy of **Morton Grove Pharmaceuticals, Inc.'s Reply in Support of Its Motion to Dismiss the National Pediculosis Association, Inc.'s Counterclaim** to be served on counsel of record via ECF electronic filing:

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